

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Osamu HONMOU et al.

Title: INTERNALLY ADMINISTERED
THERAPEUTIC AGENTS FOR CRANIAL
NERVE DISEASES COMPRISING
MESENCHYMAL CELLS AS AN ACTIVE
INGREDIENT (As Amended)

Appl. No.: 10/562,202

Filing Date: 6/25/2004

Examiner: Unassigned

Art Unit: Unassigned

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

English abstracts of the foreign-language patent documents are provided. The relevance of each foreign language literature reference is discussed in the specification. The absence of full English translations does not relieve the PTO from its duty to consider the submitted foreign language documents (37 CFR §1.98 and MPEP §609).

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

Respectfully submitted,

Date April 13, 2006

By Matthew Mulkeen

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for Stephen B. Maebius Matthew Mulkeen
Attorney for Applicant
Registration No. 35,264 Reg. No. 16,844, 250

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
Sheet	1	of	11	Application Number	10/562,202
				Filing Date	
				First Named Inventor	HONMOU et al.
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	038873-0108

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	B1	WO	03/038075	A1	Renomedix Institute Inc.	05/08/2003		
	B2	WO	02/00849	A1	Hokkaido Technology Licensing Office Co., Ltd.	01/03/2002		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	B3	AGGARWAL, et al., "Human mesenchymal stem cells modulate allogeneic immune cell responses", Blood, Vol. 105, Number 4, pp. 1815-1822, (2005).	
	B4	AKIYAMA, et al., "Transplantation of Clonal Neural Precursor Cells Derived from Adult Human Brain Establishes Functional Peripheral Myelin in the Rat Spinal Cord", Experimental Neurology, Vol. 167, pp. 27-39 (2001).	
	B5	ARCHER, et al., "Myelination by Cryopreserved Xenografts and Allografts in the Myelin-Deficient Rat", Experimental Neurology, Vol. 125, pp. 268-277 (1994).	
	B6	AUNER, et al., "Evaluation of potential risk factors for early infectious complications after autologous peripheral blood stem cell transplantation in patients with lymphoproliferative diseases", Ann Hematol, Vol. 84, pp. 532-537 (2005)	
	B7	BANG, et al., "Autologous Mesenchymal Stem Cell Transplantation in Stroke Patients", Ann Neurol, Vol. 57, pp. 874-882 (2005).	
	B8	BARKER, et al., "Acute Stroke: Evaluation with Serial Proton MR Spectroscopic Imaging", Radiology, Vol. 192, pp. 723-732 (1994).	
	B9	BEDERSON, et al., "Evaluation of 2, 3, 5-Triphenyltetrazolium Chloride as a Stain for Detection and Quantification of Experimental Cerebral Infarction in Rats", Stroke, Vol. 17, No. 6, pp. 1304-1308 (1986).	
	B10	BENDER, et al., "Identification and Comparison of CD34-Positive Cells and Their Subpopulations From Normal Peripheral Blood and Bone Marrow Using Multicolor Flow Cytometry", Blood, Vol. 77, No. 12, pp. 2591-2596 (1991).	

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	B11	BERNSTEIN, et al., "Suppression of Human Cytotoxic T Lymphocyte Responses by Adherent Peripheral Blood Leukocytes", Annals New York Academy of Science, Vol. 532, pp. 206-213 (1988).			
	B12	BJORNSON, et al., "Turning Brain into Blood: A Hematopoietic Fate Adopted by Adult Neural Stem Cells in Vivo", Science, Vol. 283, pp. 534-537 (1999).			
	B13	BLAKEMORE, et al., "Extensive Oligodendrocyte Remyelination following Injection of Cultured Central Nervous System Cells into Demyelinating Lesions in Adult Central Nervous System", Dev. Neurosci., Vol. 10, pp. 1-11 (1988).			
	B14	WIESEL, et al., "Remyelination of CNS axons by Schwann cells transplanted from the sciatic nerve", Nature, Vol. 266, p. 68-69, (1977).			
	B15	Brown, et al., "Factors That Influence the Collection and Enraftment of Allogeneic Peripheral-Blood Stem Cells in Patients With Hematologic Malignancies", Journal of Clinical Oncology, Vol. 15, No. 9, pp. 3067-3074 (1997).			
	B16	CHALMERS-REDMAN, et al., "IN VITRO Propagation And Inducible Differentiation of Multipotential Progenitor Cells From Human Fetal Brain", Neuroscience, Vol. 76, No. 4, pp. 1121-1128 (1997).			
	B17	CHEN, et al., "Therapeutic benefit of intracerebral transplantation of bone marrow stromal cells after cerebral ischemia in rats", Journal of the Neurological Sciences, Vol. 189, pp. 49-57 (2001).			
	B18	CHOPP, et al., "Spinal cord injury in rat: treatment with bone marrow stromal cell transplantation", NeuronReport, Vol. 11, No. 13, pp. 3001-3005 (2000).			
	B19	DESHARI, et al., "Enhanced antitumor effect of RGD fiber-modified adenovirus for gene therapy of oral cancer", Cancer Gene Therapy, Vol. 10, pp. 75-85 (2003).			

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	B20	ESCOLAR, et al., "Transplantation of Umbilical-Cord Blood in Babies with Infantile Krabbe's Disease", The New England Journal of Medicine", pp. 2069-81 (2005).			
	B21	FLAX, et al., "Engraftable human neural stem cells respond to developmental cues, replace neurons, and express foreign genes", Nature Biotechnology, Vol. 16, pp. 1033-1039 (1988).			
	B22	FRANKLIN, et al., "Schwann Cell-Like Myelination Following Transplantation of an Olfactory Bulb-Ensheathing Cell Line Into Areas of Demyelination in the Adult CNS", GLIA, Vol. 17, pp. 217-224 (1996).			
	B23	FRIEDENSTEIN, A.J., "Precursor Cells of Mechanocytes", International Review of Cytology, 1976, vol. 47, pp. 327-359.			
	B24	GAGE, et al., "Survival and differentiation of adult neuronal progenitor cells transplanted to the adult brain", Proc. Natl. Acad. Sci., Vol. 92, pp. 11879-11883 (1995).			
	B25	GAVRIELI, et al., "Identification of Programmed Cell Death In Situ via Specific Labeling of Nuclear DNA Fragmentation", The Journal of Cell Biology, Volume 119, No. 3, pp. 493-501 (1992).			
	B26	GOTO, et al., "GABA Receptor Agonist Promotes Reformation of the Striatonigral Pathway by Transplant Derived from Fetal Striatal Primordia in the Lesioned Striatum", Experimental Neurology, Vol. 147, pp. 503-509 (1997).			
	B27	GUMPEL, et al., "Transplantation of Human Embryonic Oligodendrocytes into Shiverer Brain", Annals New York Academy of Sciences, Vol. 495, pp. 70-85 (1987).			

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				First Named Inventor	HONMOU et al.
				Group Art Unit	Unassigned
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	B28	HAMANO, et al., "Angiogenesis Induced by the Implantation of Self-Bone Marrow Cells: A New Material for Therapeutic Angiogenesis", Cell Transplantation, Vol. 9, pp. 439-443 (2000).	
	B29	HAYASHI, et al., "Reduction of Ischemic Damage by Application of Vascular Endothelial Growth Factor in Rat Brain After Transient Ischemia", Journal of Cerebral Blood Flow and Metabolism, Vol. 18, pp. 887-895 (1998).	
	B30	HIROUCHI et al., "Current state on development of neuroprotective agents for cerebral ischemia," Folia Pharmacol. Jpn., Vol. 120, pp. 107-113 (2002).	
	B31	HONMA, et al., Intravenous infusion of immortalized human mesenchymal stem cells protects against injury in a cerebral ischemia model in adult rat", Experimental Neurology, pp. 1-11 (2005).	
	B32	HONMOU, et al., "Restoration of Normal Conduction Properties in Demyelinated Spinal Cord Axons in the Adult Rat by Transplantation of Exogenous Schwann Cells", The Journal of Neuroscience, Vol. 16, pp. 3199-3208 (1996).	
	B33	HUSS, et al., "Evidence of Peripheral Blood-Derived, Plastic-Adherent CD34 ^{-low} Hematopoietic Stem Cell Clones with Mesenchymal Stem Cell Characteristics", Stem Cells, Vol., 18, pp. 252-260 (2000).	
	B34	Iihoshi, et al., "A therapeutic window for intravenous administration of autologous bone marrow after cerebral ischemia in adult rats", Brain Research, Vol. 1007, pp. 1-9 (2004).	
	B35	IMAIIZUMI, et al., "Transplanted Olfactory Ensheathing Cells Remyelinate and Enhance Axonal Conduction in the Demyelinated Dorsal Columns of the Rat Spinal Cord", The Journal of Neuroscience, Vol. 18, pp. 6176-6185 (1998).	

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	B36	INOUE et al., "Comparative Analysis of Remyelinating Potential of Focal and Intravenous Administration of Autologous Bone Marrow Cells Into the Rat Demyelinated Spinal Cord," GLIA, 2003, pp. 111-118, Vol. 44.	
	B37	IWADATE et al., "Induction of Immunity in Peripheral Tissues Combined with Intracerebral Transplantation of Interleukin-2-producing Cells Eliminates Established Brain Tumors," Cancer Research, Dec. 15, 2001, pp. 8769-8774, Vol. 61.	
	B38	KANEGAE et al., "Efficient gene activation in mammalian cells by using recombinant adenovirus expressing site-specific Cre recombinase," Nucleic Acids Research, 1995, pp. 3816-3821, Vol. 23, No. 19.	
	B39	KATO et al., "Transplantation of Human Olfactory Ensheathing Cells Elicits Remyelination of Demyelinated Rat Spinal Cord," GLIA, 2000, pp. 209-218, Vol. 30.	
	B40	KAWANO et al., "Ex vivo expansion of human umbilical cord hematopoietic progenitor cells using a coculture system with human telomerase catalytic subunit (<i>hTERT</i>)-transfected human stromal cells," Blood, Jan. 15, 2003, pp. 532-540, Vol. 101, No. 2.	
	B41	KEIRSTEAD et al., "Polysialylated Neural Cell Adhesion Molecule-Positive CNS Precursors Generate Both Oligodendrocytes and Schwann Cells to Remyelinate the CNS after Transplantation," J. Neurosci., Sept. 1, 1999, pp. 7529-7536, Vol. 19, No. 17.	
	B42	KOBUNE et al., "Telomerized human multipotent mesenchymal cells can differentiate into hematopoietic and cobblestone area-supporting cells," Experimental Hematology, 2003, pp. 715-722, Vol. 31, Elsevier Inc.	
	B43	KOÇ et al., "Allogeneic mesenchymal stem cell infusion for treatment of metachromatic leukodystrophy (MLD) and huerl syndrome (MPS-IH), Bone Marrow Transplantation, 2002, pp. 215-222, Vol. 30.	

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	B44	KOÇ et al., "Rapid Hematopoietic Recovery After Coinfusion of Autologous-Blood Stem Cells and Culture-Expanded Marrow Mesenchymal Stem Cells in Advanced Breast Cancer Patients Receiving High-dose Chemotherapy," J. Clin. Oncol., 2000, pp. 307-316, Vol. 18, No. 2.	
	B45	KOPEN et al., "Marrow stromal cells migrate throughout forebrain and cerebellum, and they differentiate into astrocytes after injection into neonatal mouse brains," Proc. Natl. Acad. Sci., Sept. 1999, pp. 10711-10716, Vol. 96, USA.	
	B46	KUROZUMI et al., "BDNF Gene-Modified Mesenchymal Stem Cells Promote Functional Recovery and Reduce Infarct Size in the Rat Middle Cerebral Artery Occlusion Model," Molecular Therapy, Feb. 2004, pp. 189-197, Vol. 9, No. 2.	
	B47	LOIS et al., "Proliferating subventricular zone cells in the adult mammalian forebrain can differentiate into neurons and glia," Proc. Natl. Acad. Sci., Mar. 1993, pp. 2074-2077, Vol. 90, USA	
	B48	LONGA et al., "Reversible Middle Cerebral Artery Occlusion Without Craniectomy in Rats," Stroke, January 1989, vol. 20, no. 1, pp. 84-91.	
	B49	MAJUMDAR et al., "Phenotypic and Functional Comparison of Cultures of Marrow-Derived Mesenchymal Stem Cells (MSCs) and Stromal Cells," J. Cell. Physiol., 1998, pp. 57-66, Vol. 176.	
	B50	J. MOKRY, "Experimental Models and Behavioural Tests Used in the Study of Parkinson's Disease," Physiol. Res., 1995, pp. 143-150, Vol. 44, No. 3.	
	B51	R. MORRIS, "Spatial Localization Does Not Require the Presence of Local Cues," Learning and Motivation, 1981, pp. 239-260, Vol. 12.	

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	B52	MORSHEAD et al., "Neural Stem Cells in the Adult Mammalian Forebrain: A Relatively Quiescent Subpopulation of Subependymal Cells," <i>Neuron</i> , Nov. 1994, pp. 1071-1082, Vol. 13.	
	B53	MOYER et al., "Culture, Expansion, and Transplantation of Human Fetal Neural Progenitor Cells," <i>Transplantation Proceedings</i> , 1997, pp. 2040-2041, Vol. 29, Elsevier.	
	B54	NAKAGAWA et al., "Persistent and Secondary Adenovirus-Mediated Hepatic Gene Expression Using Adenovirus Vector Containing CTLA4IgG," <i>Hum.Gene Ther.</i> , Aug. 10, 1998, pp. 1739-1745, Vol. 9, No. 12, Mary Ann Liebert, Inc.	
	B55	NAKAMURA et al., "Effective Gene Transfer to Human Melanomas via Integrin-Targeted Adenoviral Vectors," <i>Hum.Gene Ther.</i> , Mar. 20, 2002, pp. 613-626, Vol. 13.	
	B56	NAKAMURA et al., "Adoptive Immunotherapy with Murine Tumor-specific T Lymphocytes Engineered to Secrete Interleukin 2," <i>Cancer Research</i> , Nov. 15, 1994, pp. 5757-5760, Vol. 54, No. 22.	
	B57	NAMBA et al., "Evaluation of the Bystander Effect in Experimental Brain Tumors Bearing Herpes Simplex Virus-Thymidine Kinase Gene by Serial Magnetic Resonance Imaging," <i>Hum. Gene Ther.</i> , Oct. 1, 1996, pp. 1847-1852, Vol. 7, No. 15, Mary Ann Liebert, Inc.	
	B58	NEUMANN-HAEFELIN et al., "Serial MRI After Transient Focal Cerebral Ischemia in Rats," <i>Stroke</i> , Aug. 2000, pp. 1965-1973.	
	B59	NIWA et al., "Efficient selection for high-expression transfectants with a novel eukaryotic vector," <i>Gene</i> , 1991, pp. 193-199, Vol. 108.	

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Sheet	8	of	11	Application Number	10/562,202
				Filing Date	
				First Named Inventor	HONMOU et al.
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	038873-0108

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	B60	NOMURA et al., "I.V. Infusion of Brain-Derived Neurotrophic Factor Gene-Modified Human Mesenchymal Stem Cells Protects Against Injury in a Cerebral Ischemia Model in Adult Rat," <i>Neuroscience</i> , 2005, pp. 161-169, Vol. 136.	
	B61	NYBERG-HOFFMAN et al., "Sensitivity and reproducibility in adenoviral infectious titer determination," <i>Nature Medicine</i> , July 1997, pp. 808-811, Vol. 3, No. 7.	
	B62	OHLSSON et al., "Environment Influences Functional Outcome of Cerebral Infarction in Rats," <i>Stroke</i> , Apr. 1995, pp. 644-649, Vol. 26, No. 4.	
	B63	PAXINOS et al., "Bregma, lambda and the interaural midpoint in stereotaxic surgery with rats of different sex, strain and weight," <i>J. Neurosci. Methods</i> , 1985, pp. 139-143, Vol. 13, Elsevier.	
	B64	PLUCHINO et al., "Neurosphere-derived multipotent precursors promote neuroprotection by an immunomodulatory mechanism," <i>Nature</i> , July 14, 2005, pp. 266-271, Vol. 436.	
	B65	PLUCHINO et al., "Injection of adult neurospheres induces recovery in a chronic model of multiple sclerosis," <i>Nature</i> , Apr. 17, 2003, pp. 688-694, Vol. 422.	
	B66	PROCKOP et al., "One strategy for cell and gene therapy: Harnessing the power of adult stem cells to repair tissues," <i>PNAS</i> , Sept. 30, 2003, pp. 11917-11923, Vol. 100, Suppl. 1.	
	B67	D. PROCKOP, "Marrow Stromal Cells as Stem Cells for Nonhematopoietic Tissues," <i>Science</i> , Apr. 4, 1997, pp. 71-74, Vol. 276.	

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	B68	REYNOLDS et al., "Generation of Neurons and Astrocytes from Isolated Cells of the Adult Mammalian Central Nervous System," Science, Mar. 27, 1992, pp. 1707-1710, Vol. 255.	
	B69	RHINES et al., "Local Immunotherapy with Interleukin-2 Delivered from Biodegradable Polymer Microspheres Combined with Interstitial Chemotherapy: A Novel Treatment for Experimental Malignant Glioma," Neurosurgery, Apr. 2003, pp. 872-880, Vol. 52, No. 4.	
	B70	ROCHEFORT et al., "Influence of hypoxia on the domiciliation of Mesenchymal Stem Cells after infusion into rats: possibilities of targeting pulmonary artery remodeling via cells therapies?" Respiratory Research, 2005, pp. 1-13, Vol. 6, No. 125.	
	B71	SASAKI et al., "Protection of Corticospinal Tract Neurons After Dorsal Spinal Cord Transection and Engraftment of Olfactory Ensheathing Cells," GLIA, 2006, pp. 352-359, Vol. 53.	
	B72	SASAKI et al., "Transplantation of an Acutely Isolated Bone Marrow Fraction Repairs Demyelinated Adult Rat Spinal Cord Axons," GLIA, 2001, pp. 26-34, Vol. 35.	
	B73	STABA et al., "Cord-Blood Transplants from Unrelated Donors in Patients with Hurler's Syndrome," N. Engl. J. Med., May 6, 2004, pp. 1960-1969, Vol. 350, No. 19.	
	B74	SVENDSEN et al., "Long-Term Survival of Human Central Nervous System Progenitor Cells Transplanted into a Rat Model of Parkinson's Disease," Experimental Neurology, 1997, pp. 135-146, Vol. 148, Article No. EN976634.	
	B75	TAKIGUCHI et al., "CTLA4IgG Gene Delivery Prevents Autoantibody Production and Lupus Nephritis in MRL/lpr Mice," Life Sciences, 2000, pp. 991-1001, Vol. 66, No. 11, Elsevier.	

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	B76	TAMURA et al., "Focal cerebral infarction in the rat: I. Operative technique and physiological monitorings for chronic model," No To Shinkei, 1986, vol. 38, no. 8, pp. 747-751.	
	B77	TILLE et al., "Mesenchymal Cells Potentiate Vascular Endothelial Growth Factor-Induced Angiogenesis <i>in Vitro</i> ," Experimental Cell Research, 2002, pp. 179-191, Vol. 280.	
	B78	TOMA et al., "Human Mesenchymal Stem Cells Differentiate to a Cardiomyocyte Phenotype in the Adult Murine Heart," Circulation, Jan. 1/8, 2002, pp. 93-98.	
	B79	TONDREAU et al., "Mesenchymal Stem Cells Derived from CD133-Positive Cells in Mobilized Peripheral Blood and Cord Blood: Proliferation, Oct4 Expression, and Plasticity," Stem Cells, 2005, pp. 1105-1112, Vol. 23.	
	B80	TSUDA et al., "Efficient BMP2 Gene Transfer and Bone Formation of Mesenchymal Stem Cells by a Fiber-Mutant Adenoviral Vector," Mole. Therapy, Mar. 2003, pp. 354-365, Vol. 7, No. 3.	
	B81	UTZSCHNEIDER et al., "Transplantation of glial cells enhances action potential conduction of myelinated spinal cord axons in the myelin-deficient rat," Proc. Natl. Acad. Sci., Jan. 1994, pp. 53-57, Vol. 91, USA.	
	B82	VILLARON et al., "Mesenchymal stem cells are present in peripheral blood and can engraft after allogeneic hematopoietic stem cell transplantation," Haematologica, Dec. 2004, pp. 1421-1427, Vol. 89, No. 12.	
	B83	WILLING et al., "Mobilized Peripheral Blood Cells Administered Intravenously Produce Functional Recovery in Stroke," Cell Transplant., 2003, pp. 449-454, Vol. 12, USA.	

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	B84	YANDAVA et al., "Global' cell replacement is feasible via neural stem cell transplantation: Evidence from the dysmyelinated shiverer mouse brain," Proc. Natl. Acad. Sci., June 1999, pp. 7029-7034, Vol. 96, USA.		T ⁶
	B85	WOODBURY et al., "Adult Rat and Human Bone Marrow Stromal Cells Differentiate Into Neurons," J. Neurosci. Res., 2000, pp. 364-370, Vol. 61.		
	B86	YAMAUCHI et al., "Pre-administration of angiopoietin-1 followed by VEGF induces functional and mature vascular formation in a rabbit ischemic model," J. Gene Med., 2003, pp. 994-1004, Vol. 5.		
	B87	ZHANG et al., "Human bone marrow stromal cell treatment improves neurological functional recovery in EAE mice," Exper. Neurology, 2005, pp. 16-26, Vol. 195, Elsevier.		
	B88	ZVAILER et al., "Mesenchymal precursor cells in the blood of normal individuals," Arthritis Res., 2000, pp. 477-488, Vol. 2, No. 6.		

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